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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Applicati n N .	Applicant(s)	
	10/677,694	NAJAFI ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE f this communication appears on the cov r sheet with th c rrespond nce address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44,46-63 and 65-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,32,35-70* is/are rejected.

7)☒ Claim(s) *31,33,34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This is a non-final Office action. The indicated allowability of claims 15, 16, 32, and 59-63 is withdrawn in view of the rejections presented below. The finality of the previous Office action is also withdrawn.

Claim Objections

Claims 15 and 65-67 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 15 merely repeats the limitation that was inserted at the end claim 1.

Claim 65 merely repeats lines 17-18 of claim 2.

Claim 66 merely repeats lines 19-21 of claim 2.

Claim 67 merely repeats lines 22-23 of claim 2.

Claim 2 is objected to because of the following informalities:

On line 12 of claim 2, "mechanism," should be replaced with "mechanism comprising a pacing/ICD unit". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, 7, 8, 10, 13, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 32, 35, 36, 39, 40, 49-56, 58-63, 68, 71, and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification lacks sufficient description of an embodiment of the invention in which the system includes an implantable sensing device, a non-implantable readout device allowing telecommunication and powering of the sensing device, a pacing/ICD unit, an external unit solely for transmitting power to the sensing device, and a external reader which receives data from the sensing device and retransmits the data to the pacing/ICD unit. The description of the closed-loop pacing/ICD tuning system on p.11 of the specification describes an embodiment comprising an implanted sensor, a pacing/ICD unit, and either an external unit solely for transmitting power *or* an external reader for interrogating and/or powering the sensor. In the embodiment in which an external reader interrogates and/or powers the sensor, the pacing/ICD unit also may interrogate and/or power the sensor. There is no description of the system including both the external unit and the external reader. Furthermore, there is no description of the system including the non-implantable readout device in combination with any of the pacing/ICD unit, external unit, or external reader.

The instant specification lacks sufficient description of an embodiment of the invention wherein both a drug delivery device is included in the system *and* the system

is part of a closed-loop pacing/ICD tuning mechanism as claimed in claims 16 and 59-63. The specification further lacks sufficient description of an embodiment of the invention wherein the system is part of a closed-loop pacing/ICD tuning mechanism *and* is part of a closed-loop system with a left atrium to right atrium unidirectional valve for preventing the development of pulmonary edema, as claimed in claim 32. Instead, the instant specification presents three separate embodiments: one in which the system is implemented as a closed-loop pacing/ICD tuning system (on lines 3-11 of p.11 of the instant specification), one in which the system is part of closed-loop drug delivery system including a drug delivery device (on lines 12-15 of p. 11 of the instant specification), and one in which the implanted sensor data may be used as feedback for a unidirectional valve (lines 16-19 of p.11 of the instant specification). The specification lacks description of combinations of these embodiments.

Claims 2, 4, 7, 8, 10, 13, 14, 18, 20, 22, 24, 26, 28, 30, 31, 35, 36, 39, 40, 49-56, 58, 68, 71, and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 2 recites a system which appears to comprise an implantable sensing device, a non-implantable readout device allowing telecommunication and powering of the sensing device, a pacing/ICD unit, an external unit solely for transmitting power to the sensing device, and a external reader which receives data from the sensing device

and retransmits the data to the pacing/ICD unit. The specification fails to clearly explain how to make or use such a system. It is unclear why the system includes a non-implantable readout device for communication and powering of the sensor in addition to a separate external unit for powering of the sensor and a separate external reader for telecommunication with the sensor, or how all of the external units are used together in the system with respect to each other, the sensor, and the pacing/ICD unit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 9, 11, 12, 23, 25, 27, 37, 38, 41, 43, 46, 47, 57, and 59 are rejected under 35 U.S.C. 103(a) as being anticipated by US Patent No. 6,409,674 to Brockway et al. in view of Us Patent No. 4,987,897 to Funke. Brockway describes a system for monitoring at least one physiological parameter, the system comprising at least one implantable sensing device 105 and at least one non-implantable readout device 140 (figs. 1, 2, 4, and 5 of Brockway). The implantable device 105 comprises an anchoring mechanism, at least one inductor coil and at least one sensor 305 (col. 8, lines 13-15; col. 10, lines 15-25 of Brockway). The readout device 140 comprises at least one inductor coil allowing electromagnetic telecommunication and powering (col. 7, lines 42-55; col. 10, lines 15-25 of Brockway). The system may additionally include a drug-

delivery device (col. 11, lines 6-13 of Brockway), but Brockway is silent as to how the drug-delivery device functions.

However, Funke teaches a system comprising an implantable drug delivery device which receives data from an implantable blood pressure sensing device, where the drug delivery device tailors drug treatment of the patient based on the sensed pressure data (col. 10, line 1-9 of Funke). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the control of the drug delivery device of Funke with the system of Brockway, since Brockway teaches a system using an implantable blood pressure sensor and a drug delivery device, and Funke discloses appropriate communication and control of the drug delivery device in such a system.

As to the language "for monitoring . . . for diagnosis of congestive heart failure" on lines 1-2 of claim 1 and "for monitoring . . . for treatment of congestive heart failure" on lines 1-2 of claim 2, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Brockway teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Brockway is fully capable of being used for either diagnosis or treatment of congestive heart failure in a patient (col. 1, lines 38-60 of Brockway). The orientation of the sensing device upon implantation ("sensing device being implanted so that a portion of said anchoring mechanism passes through a septum of the heart and . . . a larger portion of the implantable sensing device is located in the right side of the heart and a smaller portion of the implantable sensing

device if located in the left side of the heart. . .") is similarly intended use language which cannot be relied upon to define over the prior art since Brockway teaches all of the claimed limitations and their recited relationships. The device of Brockway is certainly *capable* of being implanted in such a way as described in claim 1.

Regarding claims 9, 11, 12, 23 and 25 the system is for monitoring pressure, wherein the pressure transducer 305 may be placed in any one of the chambers of the heart and therefore may measure any right or left atrial or ventricular pressure (col. 7, lines 14-37 of Brockway). With further regard to claims 12 and 14, the system calculates the change of pressure over time (dp/dt) (col. 1, lines 30-55; col. 9, lines 33-41 of Brockway).

Regarding claim 19, a passive scheme is used (col. 10, lines 15-25 of Brockway).

Regarding claim 27 the applicants should note that the intended use of the invention cannot be relied upon to define over the prior art, since Brockway teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Brockway may certainly be used for disease management or treatment, for example (col. 14, lines 37-40 of Brockway).

Regarding claim 29, the readout device 140 is capable of closed-loop pacemaker parameter tuning to treat CHF or CHF related conditions, portable or ambulatory monitoring, data storage, and communication with other medical devices, including pacemakers, for example (figs. 1, 2, 4, and 5; col. 11, lines 14-62; col. 14, lines 30-40 of Brockway).

Regarding claims 37 and 38, the implantable device 105 is implanted using a minimally invasive outpatient technique or catheter delivery method (col. 1, line 65-col. 1, line27; col. 12, line 56-col. 13, line 17 of Brockway).

Regarding claims 41, 43, 46, and 47 the implantable sensing device 105 uses an anchoring mechanism including a screw 312A, tine 312B, 312D, or stent 312C (figs. 3A-D; col. 8, lines 26-52 of Brockway). With further regard to claims 43, 45, 51, and 53, the anchor 312A, 312B is capable of passing through an atrial septum. With further regard to claim 46, the anchoring mechanism is a helical screw 312A (fig. 3A of Brockway). With further regard to claim 47, the anchoring mechanism is a tine 312D that expands (figs. 3D and 7; col. 8, lines 45-52; col. 13, lines 43-47 of Brockway), wherein the expandable tine 312D is capable of catching on a trabecular area of the heart.

Regarding claim 57, the implantable sensing device 105 is augmented with a pacing stimulator or defibrillator 400, for example (figs. 4 & 5; col. 11, lines 14-62 of Brockway).

Regarding claim 59, the system is part of a closed-loop pacing/ICD tuning mechanism where the data from the sensor 305 is sent to a patient pacemaker for tailoring of pacing/ICD function (figs. 4 & 5; col. 11, lines 14-62 of Brockway).

Claims 1, 5, 6, 9, 11, 19, 23, 25, 27, 29, 37, 38, 41-44, 46-48, 57, 69 and 70 are rejected under 35 U.S.C. 103(a) as being anticipated by US Patent No. 4,080,966 to McNally et al. in view of US Patent No. 6,636,769 to Govari et al. McNally teaches a sensing device for sensing the blood pressure of a patient, wherein the sensing device

sends data directly to a drug delivery device to tailor treatment of the patient (fig. 3; col. 5, line 15-col. 6, line 53 of McNally). McNally lacks the sensing device being implantable and further lacks a non-implantable readout device.

However, Govari teaches a system for monitoring one or more physiological parameters for diagnosis or treatment of congestive heart failure (CHF) within a patient. The system comprises at least one implantable sensing device adapted to be implanted in a cavity of the patient's cardiovascular system and that senses blood pressure. The sensing device comprises an anchoring mechanism and has at least one inductor coil 68 and at least one sensor. The sensing device of Govari may be implanted in the body such that a portion of the anchoring mechanism passes through the septum of the heart (figs. 1, 3-5, 11; col. 5, lines 39-47; col. 6, lines 22-col. 7, line 21; col. 9, lines 17-20; col. 10, lines 1-60 of Govari). A non-implantable readout device 140, has at least one inductor coil 162 having telemetric means for electromagnetic telecommunication and/or electromagnetic wireless powering (fig. 8; col. 7, line 58-col. 8, line 5; col. 8, lines 33-65 of Govari). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the system of Govari as the sensing device of McNally, as it would merely be the substitution of one known blood pressure sensing device for another.

As to the limitation "a larger portion of said implantable sensing device is located on the right side of the heart and a smaller portion of said implantable sensing device is located in the left side of the heart and includes the at least one sensor", Fig. 11 of Govari shows the larger portion of the sensing device being located on *a* right side of

the heart. While Govari discloses 410 to be the left atrium and 415 the right atrium in figure 10, the applicants should note that the orientation of the device during implantation is merely "intended use" language that cannot be relied upon to define over the prior art since Govari teaches all of the claim limitations and their recited relationships. The device of Govari is certainly capable of being implanted so that the larger portion of the device is placed in either the left or right sides of the heart.

Regarding claims 5 and 6, the sensing device 50 includes a battery, wherein the charge capacitor 114 acts as a battery (col. 7, line 48-col. 8, line 5 of Govari). With further regard to claim 6, the battery or charge capacitor 114 is rechargeable using wireless means (col. 7, line 48-col. 8, line 5 of Govari).

Regarding claims 9, 11, and 23, the sensor 50 may sense pressure (col. 6, lines 5-14; col. 9, lines 17-40; col. 10, lines 50-60 of Govari). With further regard to claim 11, the sensor 50 may measure any left ventricular, left atrial, right ventricular, or right atrial pressure (col. 10, lines 50-60 of Govari).

Regarding claim 19, a passive scheme is used (col. 8, lines 38-46 of Govari).

Regarding claim 25, the device may be located at the atrial septum, left or right atrium, or left or right ventricle of the heart (figs. 10 & 11; col. 10,lines 50-67 of Govari).

Regarding claim 27 the applicants should note that the intended use of the invention cannot be relied upon to define over the prior art, since Govari teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Govari may certainly be used to determine drug treatment for a patient or for disease management, for example.

Regarding claim 29, the readout device 140 is capable of performing remote monitoring of congestive heart failure patients or of portable or ambulatory monitoring or diagnosis (col. 10, lines 2-67 of Govari).

Regarding claims 37 and 38, the implantable device 50 is capable of being implanted using a minimally invasive outpatient technique or catheter delivery method (cols. 11 and 12 of Govari).

Regarding claims 41-44 and 46-48, the implantable device 50 uses an anchoring mechanism including a septal occluding device, a screw, or a tine (figs. 1, 3, 4, and 11; col. 6, lines 39-65; col. 10, lines 59-60 of Govari). With further regard to claims 42-45 and 50-53, the anchor passes through a septum wall and opens on one side of the wall, clamping the device to the wall (fig. 11; col. 10, lines 59-60 of Govari). With further regard to claims 44 and 52, the anchoring mechanism utilizes two umbrella shaped anchors 64, one on each side, which anchor the sensing device 50 (fig. 11 of Govari). With further regard to claims 45 and 53, a larger portion of the implantable device 50 is located on the right side of the heart while a smaller portion is located in the left side of the heart (fig. 11 of Govari). With further regard to claims 46 and 54, the anchoring mechanism is a helical screw (fig. 3 of Govari). With further regard to claims 48 and 56, the anchoring mechanism is made from nitinol (col. 6, lines 43-45 of Govari).

Regarding claim 57, the implantable sensing device 50 is augmented with a radiation emitting source 100 (fig. 6A & B; col. 7, lines 15-17 of Govari).

Regarding claims 69 and 70, at least a portion of the implantable sensing device 50 is coated with one or more layers of thin coating 52 (fig. 5; col. 5, lines 49-51 of Govari), wherein the coating comprises titanium and polysilicon.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over McNally in view of Govari, as applied to claims 1, 5, 6, 9, 11, 19, 23, 25, 27, 29, 37, 38, 41-44, 46-48, 57, 69 and 70 above, and further in view of US Patent No. 5,207,103 to Wise et al. Govari teaches the sensor as being a deflecting membrane in conjunction with an LED. However, Wise teaches using a capacitive pressure sensor in an implantable medical device (abstract; col. 5, line 10-col. 6, line 3 of Wise). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the capacitive sensor of Wise in the device of McNally, as modified, as it would be the mere substitution of one known means for measuring pressure for another.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over McNally in view of Govari, as applied to claims 1, 5, 6, 9, 11, 19, 23, 25, 27, 29, 37, 38, 41-44, 46-48, 57, 69 and 70 above, and further in view of US Patent No. 6,287,253 to Ortega. Govari uses a passive scheme rather than a resonant scheme to couple the sensing device to the readout device. However, Ortega teaches a medical sensor using a resonant scheme to couple a sensing device with a readout device (fig. 4; col. 8, line 19-37 of Ortega). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the resonant scheme of Ortega in place of the passive

scheme of McNally, as modified, as it would merely be the substitution of one known communication scheme for another.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over McNally in view of Govari, as applied to claims 1, 5, 6, 9, 11, 19, 23, 25, 27, 29, 37, 38, 41-44, 46-48, 57, 69 and 70 above, and further in view of US Patent No. 6,231,516 to Keilman et al. Govari teaches using a passive scheme to couple the sensing device and readout device. However, Keilman teaches using either a passive or an active scheme to couple a sensing device and a readout device (col. 8, lines 20-39; col. 13, lines 54-65 of Keilman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use an active scheme in place of the passive scheme of McNally, as modified, since Keilman teaches both schemes to be functionally equivalent.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

No art has been applied to claims 2, 4, 7, 8, 10, 13, 14, 18, 20, 22, 24, 26, 28, 30, 31, 35, 36, 39, 40, 49-56, 58, 68, 71, and 72, but the art rejection will be revisited upon resolution of the rejection under 35 U.S.C. 112, 1st paragraph.

Claims 31, 33, and 34 are allowed.

The reason for the allowability of claim 31 was addressed in a previous Office action filed 11/2/05 and is repeated below. The reason for the allowability of claims 33 and 34 was addressed in a previous Office action filed 4/20/06 and is repeated below.

The following is a statement of reasons for the indication of allowable subject matter:

With regard to claim 31, the prior art of record fails to teach or fairly suggest a system for monitoring at least one physiological parameter for diagnosis or treatment of congestive heart failure within a patient comprising an implantable sensing device, having a sensor and an inductor coil, and a non-implantable readout device, wherein the system is incorporated into a closed-loop system with a left atrium to right atrium unidirectional valve for preventing the development of pulmonary edema, in combination with all of the other limitations of the claims.

Regarding claims 33 and 34, the prior art of record fails to teach or fairly suggest a system wherein the non-implantable readout device includes a barometric pressure sensor, in combination with all of the other limitations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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